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Safety, tolerability and efficacy of LEGA-Kid® mechanical percussion device versus conventional chest physiotherapy in children: a randomised, single-blind controlled study

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ABSTRACT

Introduction: Chest physiotherapy (CPT) may benefit children aged < 5 years who suffer from lower respiratory tract infection (LRTI). However, its effects are technique-dependent. This study aimed to determine whether mechanical CPT using the LEGA-Kid® mechanical percussion device is superior to manual CPT in children with LRTI.

Methods: Children aged 5 months to 5 years who were admitted and referred for CPT from January to April 2017 were randomised to either manual CPT or mechanical CPT with LEGA-Kid®. Outcomes measured at pre-intervention and 2 hours post-intervention were respiratory rate (RR), oxygen saturation and modified Respiratory Distress Assessment Instrument (mRDAI) score.

Results: All 30 enrolled patients had significant reduction in post-intervention RR and mRDAI scores. There was an 8% reduction in RR for the manual CPT group ($p = 0.002$) and a 16.5% reduction in the mechanical CPT group ($p = 0.0001$), with a significantly greater reduction in the latter ($p = 0.024$). mRDAI scores decreased by 2.96 in the manual group ($p = 0.0001$) and 3.62 in the mechanical group ($p = 0.002$), with no significant difference between the groups. There was no significant improvement in oxygen saturation, and no adverse events were observed after CPT.

Conclusion: Children receiving either manual or mechanical CPT showed improvements in respiratory distress symptoms with no adverse effects. A combined strategy of nebulised hypertonic saline followed by CPT for LRTI removes airway secretions and results in improvements of moderately severe respiratory distress. The LEGA-Kid mechanical CPT method was superior in reducing RR.

Keywords: children, lower respiratory tract infections, manual chest physiotherapy, mechanical percussor, nebulised hypertonic saline

INTRODUCTION

Lower respiratory tract infections (LRTIs) are common in children below the age of 5 years and a leading cause of hospital admissions. LRTIs are associated with increased morbidity and mortality.(1) Most infections are viral in origin and associated with copious thick secretions. As a consequence of this, the airway becomes obstructed, resulting in severe respiratory distress and ventilation-perfusion mismatch.(2) The presence of airway oedema also increases airway resistance, thereby worsening hypoxia. The consequences of mechanical obstruction include reduced tidal volume, increased work of breathing and retained secretions, which further exacerbate respiratory distress.

Chest physiotherapy (CPT) assists in mucociliary clearance, which reduces airway resistance and improves ventilation.(3) Newer CPT methods, such as forced exhalation with an open glottis(4) and slow-flow techniques,(5,6) have shown short-term benefits to respiratory symptoms from bronchial obstruction, without impact on duration of hospitalisation. In patients who are hospitalised with acute bronchiolitis, conventional CPT and expiratory acceleration flow techniques have shown short-term improvements in respiratory distress scores and positive parental satisfaction.(7) Conventional CPT and prolonged slow expiration techniques were effective in reducing clinical scores 48 hours after intervention when compared to only upper airway suctioning in patients with respiratory syncytial virus bronchiolitis of moderate severity.(8) However, its use has been limited because CPT requires an experienced therapist to perform.

A Cochrane (2016) analysis of 12 randomised controlled trials compared physiotherapy with no intervention in mild, moderate and severe acute bronchiolitis patients.(9) Physiotherapy techniques included conventional percussion with vibration plus postural drainage and passive flow-orientated expiratory techniques. Both techniques failed to improve severity status and time to recovery. However, one trial observed a small

improvement in the Wang clinical score immediately after the intervention in patients with moderately severe acute bronchiolitis.(8) The authors of the review concluded that these physiotherapy techniques could not be used as standard clinical practice for hospitalised patients with severe bronchiolitis, and instead recommended exploring the combination of chest physiotherapy with salbutamol or hypertonic saline in patients with mild to moderate acute bronchiolitis.(9)

Effective CPT techniques require skilled personnel and may be difficult to perform in young children. LEGA, a mechanical device designed by Formedic Technology Sdn Bhd, Malaysia, has been used as an aid for CPT. This machine is a handheld battery-operated percussor that provides clapping to the chest wall to mimic manual hand percussion. A randomised controlled cross-over study evaluating the efficacy and safety of LEGA compared to conventional CPT in adults with chronic obstructive pulmonary disease showed the device to be effective in generating cough and expectoration of sputum. The device was well tolerated and patients were able to use it independent of a chest physiotherapist.(10)

A similar but smaller device (LEGA-Kid®) has been designed by Formedic Technology for use in children weighing 5–15 kg. It produces rotational movements with a predetermined frequency that creates percussion and vibration forces when in contact with the chest wall. The generated force travels through the chest wall and helps to loosen secretions. We hypothesised that LEGA-Kid would be as effective as manual CPT for mucus clearance, thereby reducing respiratory distress without causing significant patient distress. This study sought to compare the safety, tolerability and efficacy of LEGA-Kid with that of manual CPT in children with LRTI.

METHODS

This single-blind, randomised controlled study was conducted in the paediatric wards of University Malaya Medical Centre (UMMC). Eligible children were randomly allocated to manual (control group) or mechanical CPT (study group) after informed consent was obtained. Approval from the UMMC Medical Ethics Committee was obtained prior to the start of the study (ID No 20166-2502). The study was registered with the National Medical Research Registry (NMRR) of Malaysia (NMRR-16-2803-32022).

Children aged 5 months to 5 years, weighing between 5 kg and 15 kg, who were admitted with symptoms of LRTI and referred for CPT by the managing doctors were included into the study. Children were excluded if they had severe respiratory distress or heart failure, bone disease, thrombocytopenia, or a modified Respiratory Distress Assessment Instrument (mRDAI) score ≤ 6 (Table I).

Table I. Modified Respiratory Distress Assessment Instrument scale: wheezing, crackles and retractions.

	Point					Maximum point
	0	**1**	**2**	**3**	**4**	
Wheezing						
Expiration	None	End	½	¾	All	4
Inspiration	None	Part	All			2
Location	None	Segmental: ≤ 2 of 4 lung fields	Diffuse: ≥ 3 of 4 lung fields			2
Crackles						
Expiration	None	Part	All			2
Inspiration	None	Part	All			2
Location	None	Segmental: ≤ 2 of 4 lung fields	Diffuse: ≥ 3 of 4 lung fields			2
Retraction						
Supraclavicular	None	Mild	Moderate	Marked		3
Intercostal	None	Mild	Moderate	Marked		3
Subcostal	None	Mild	Moderate	Marked		3

Within each variable, the subscores are summed to give a total score. The maximum total points are 8 for wheezing, 6 for crackles and 9 for retraction.

The patients were randomised to either manual or mechanical CPT using an online software, Research Randomizer 4.0,[11] in a ratio of 1:1 using permuted blocks of 4. The number '1' was assigned to the first eligible participant, the number '2' to the second, and so on till number '30'. This was a single-blinded study where the intervention arm was known to the participants and physiotherapist, but not to the physician performing the pre- and post-intervention evaluations.

Nebulised 3% hypertonic saline (4 mL over 15 minutes) was administered to all patients before the physiotherapy session. CPT, together with postural drainage, was performed by an experienced paediatric chest physiotherapist. The following steps were incorporated: (a) an assessment of the patient's condition, vital signs and auscultation to identify the involved lung segment was done; (b) the patient was placed according to the postural drainage positions; (c) chest percussion and vibration manually or with LEGA-Kid device was done on the chest area; (d) removal or expectoration of mucus was done by gentle oral/nasal suction and provoked cough; and (e) technique with localised breathing was incorporated to enhance expansion of the specific lung segment.

Mechanical CPT involved application of the percussor firmly and at right angles to the chest wall to make the voice quiver. The selected frequency was indicated by the numbers 1 to 10; the lower numbers signified percussions and higher numbers vibrations. Each physiotherapy session lasted for 15–20 minutes during which the patients were shown their favourite videos and toys. Post CPT, positioning was performed to improve chest expansion. Oxygen therapy was continued as at T_0, pre-intervention. Bronchodilator therapy was avoided during the intervention period, which was about 3 hours.

All patients received a baseline evaluation at enrolment, and pre-intervention (T_0) and 2-hour post-intervention (T_{120}) evaluations by a trained physician who was blinded to the method of CPT. The primary outcome measures evaluated were temperature, heart rate, RR,

pulse oximetry with a Nellcor oximeter after being in room air for 5 minutes, and modified Respiratory Distress Assessment Instrument (mRDAI). The mRDAI is a modification of the RDAI, which rates wheezing and respiratory distress on a scale of 0 to 17. The addition of assessment of crackles gives a total score of 23 (Table I). Both RDAI and mRDAI have shown good inter-observer reliability.[12] The Wang severity score,[13] which assesses wheezing, RR, retractions and general condition, was evaluated daily. Each clinical sign was scored from 0 to 3 (possible total range of scores: 0–12); the higher the score, the more severe the disease. The Wang clinical severity score has been reported to have good inter-rater reliability, with an intraclass correlation coefficient of 0.99.[14]

During the intervention, a research assistant monitored the heart rate and oxygen saturation and also looked out for any adverse events such as bradycardia, desaturation and vomiting. The secondary outcome measures were length of hospital stay and FLACC (Face, Leg, Activity, Cry, Consolability) scale to assess level of distress[15] at T_0, during intervention (T_{CPT}) and at T_{120}. The FLACC scale evaluates pain and discomfort in the paediatric age group. It has a score of 0 to 10, where 0 indicates relaxed and comfortable, 1–3 mild distress, 4–6 moderate pain and 7–10 severe distress.

CPT was carried out daily until the mRDAI score was ≤ 6 or until hospital discharge. Typical care involving the type of respiratory support and oxygen supplementation was determined by the ward clinicians, who were blinded to the method of CPT. Oxygen therapy was delivered via nasal cannula or high flow nasal cannula. Target oxygen saturation was 95%, while the choice of oxygen delivery was tailored to the patient's RR and the presence of retractions.

Data was entered using IBM SPSS Statistics version 23.0 (IBM Corp, Armonk, NY, USA). To reach the statistical effect of 80% power and 5% significance, a sample size of 30 was required – 15 in the manual CPT arm and 15 in the mechanical arm (LEGA-Kid). Non-

parametric data was analysed using the Mann-Whitney *U* test, and parametric data was analysed using paired and Student's *t*-tests. Paired *t*-test was used to compare pre- and post-intervention observations in each group, while Student's *t*-test was used to compare the difference between the groups. Chi-square test was used for nominal data. One-way analysis of variance for repeated measures was used to compare the daily evolution of the Wang scores. A p-value < 0.05 was considered statistically significant.

RESULTS

A total of 30 patients were enrolled and randomised to receive either manual or mechanical CPT between 9 January 2017 and 30 April 2017. The patients completed 45 sessions in the manual group and 42 sessions in the mechanical group for a total of 87 physiotherapy sessions. The demographic data and baseline clinical characteristics of the patients are shown in Table II. The median mRDAI score and Wang clinical severity score were similar (p = 0.683) in both arms; both groups had similar severity of illness. A median mRDAI score of 11 at enrolment indicated moderately severe respiratory distress. A total of 12 patients (6 in each arm) required oxygen therapy or respiratory support during the hospitalisation period.

Table II. Demographic data and parameters at enrolment.

Demographic/parameter	**Median (IQR)/No. (%)**		**p-value**
	Manual CPT (n = 15)	**Mechanical CPT (n = 15)**	
Age (mth)	11 (7–19)	10 (8–13)	0.884
Male gender	10 (66.7)	13 (86.7)	
Weight (kg)	8.6 (7.4–9.2)	8.1 (7.3–9.2)	0.693
Diagnosis			
Acute bronchiolitis	9 (60.0)	9 (60.0)	
Bronchopneumonia	6 (40.0)	6 (40.0)	
Past history - prematurity	2 (13.3)	3 (20.0)	
Clinically significant illness	8 (53.3)	9 (60.0)	
Underlying chronic illness	3 (20)*	3 (20)†	
Home oxygen/respiratory support	2 (13.3)	1 (6.7)	
Parameter at enrolment			
Respiratory rate (breath/min)	42 (38–48)	45 (35–48)	0.819
Heart rate (beat/min)	130 (125–142)	130 (121–139)	0.803

Oxygen saturation (%)	97 (92–99)	98 (95–98)	0.641
Temperature	36.7 (36.5–37.0)	36.6 (36.4–36.9)	0.167
mRDAI score			
Crackles	5 (4–5)	4 (2–4)	
Wheeze	5 (4–5)	4 (4–5)	
Retraction	4 (3–5)	4 (3–5)	
Total mRDAI score	11 (10–12)	11 (8–12)	0.486
Wang clinical severity score	9 (7–9)	9 (7–9)	0.683
FLACC score	3 (0–6)	5 (0–6)	0.528
Treatment of current illness			
Bronchodilators	2 (13.3)	1 (6.7)	
Antibiotics	8 (53.3)	8 (53.3)	
Oxygen therapy at enrolment	6 (40)	6 (40)	
Culture positive			
Respiratory syncytial virus	2 (13.3)	1 (6.7)	
Other viral pathogens	2	1	
Bacterial pathogens	3	2	
Length of stay (n = 15)	4 (3–8)	5 (4–6)	0.683
Acute bronchiolitis (n = 9)	4 (3–7.5)	4 (3.5–5.5)	0.863
Bronchopneumonia (n = 6)	5 (3.5–9.3)	5.5 (4.75–7.8)	0.699

*Underlying chronic illnesses include *cystic fibrosis, neurodevelopmental delay, trisomy 21 and chronic lung disease; †Cerebral palsy, neurodevelopmental delay, trisomy 21 and obstructive sleep apnoea syndrome.*
CPT: chest physiotherapy; FLACC: Face, Leg, Activity, Cry, Consolability scale; IQR: interquartile range; mRDAI: modified Respiratory Distress Assessment Instrument

Patients in both the manual and mechanical groups showed significant reductions in RR and mRDAI score at T_{120} compared to T_0 (Table III). The mean reduction in RR was 3.6 breaths per minute (8% reduction, p = 0.002) in the manual group and 7.0 breaths per minute (16.5% reduction, p = 0.0001) in the mechanical group. The reduction in RR was significantly greater in the mechanical group (p = 0.024).

Similarly, there was a significant decrease in mRDAI scores between T_0 and T_{120} – 2.96 points (27.2% reduction, p = 0.0001) in the manual group and 3.62 points (34.5% reduction, p = 0.0001) in the mechanical group. Similar improvements were seen in all three components of the mRDAI score at T_{120} compared to T_0. However, the reduction in mRDAI scores in the mechanical and manual groups was not significant (p = 0.144). Children in the mechanical group showed significant improvement in oxygen saturation at T_{120} (p = 0.013) compared to the manual group (p = 0.123). However, the improvement in oxygen saturation in the mechanical and manual groups was not significant (p = 0509).

Table III. Changes in clinical characteristics of patients pre- (T_0) and post intervention (T_{120}).

Variable	Manual CPT (n = 45)				Mechanical CPT (n = 42)				p-value†
	T_0	T_{120}	$T_{120} - T_0$	p-value*	T_0	T_{120}	$T_{120} - T_0$	p-value*	
mRDAI score	10.7 ± 2.2	7.7 ± 2.5	−3.0 ± 2.1	0.0001	10.3 ± 2.1	6.5 ± 2.4	−3.6 ± 2.1	0.0001	0.144
Wheezing	2.9 ± 1.7	2.0 ±1.6	−1.0 ± 1.5	0.0001	3.1 ± 1.8	1.6 ± 1.7	−1.6 ± 1.8	0.0001	0.096
Crackles	4.0 ± 1.1	2.9 ± 1.4	−1.1 ± 1.3	0.0001	3.6 ± 1.3	2.7 ± 1.4	−0.9 ± 1.5	0.0001	0.584
Retractions	3.8 ± 0.9	2.9 ± 1.0	−0.9 ± 1.1	0.0001	3.6 ± 1.0	2.5 ± 1.1	−1.2 ± 1.0	0.0001	0.244
Respiratory rate	38.7 ± 7.7	35.1 ± 7.4	−3.6 ± 7.1	0.002	40.9 ± 7.3	34.0 ± 7.8	−7.0 ± 6.7	0.0001	**0.024**
Heart rate	127.8 ± 13.7	127.1 ± 14.1	−0.6 ± 12.1	0.722	131.2 ± 15.3	128.0 ± 14.1	−3.2 ± 14.9	0.171	0.378
SpO_2	96.6 ± 3.2	97.2 ± 3.0	0.6 ± 2.4	0.123	96.6 ± 2.6	97.5 ± 2.1	0.9 ± 2.2	0.013	0.509
Temperature	36.6 ± 0.4	36.7 ± 0.6	0.0 ± 0.6	0.757	36.6 ± 0.4	36.7 ± 0.5	0.1 ± 0.3	0.256	0.747

*Data presented as mean ± standard deviation, unless otherwise stated. *Paired t-test comparing pre- (T_0) and post (T_{120}) intervention. †Student's t-test comparing manual CPT and mechanical CPT. mRDAI: modified Respiratory Distress Assessment Instrument; SpO_2: oxygen saturation by pulse oximetry*

Table IV shows the FLACC scores at pre- (T_0), during (T_{CPT}) and post (T_{120}) intervention. For both groups of patients, the mean FLACC score did not differ considerably at T_{CPT} (manual 3.80 vs. mechanical 3.71, p = 0.86) compared to that at T_0 (3.6 vs. 3.3, p = 0.64). Mean change in FLACC score between T_0 and T_{CPT} was 0.24 (p = 0.175) in the manual group and 0.43 (p = 0.06) in the mechanical group. The difference between these two groups was not significant (p = 0.503). However, a significant reduction in the T_{120} FLACC score was observed in both groups of patients (manual 2.96, p = 0.0001 vs. mechanical 2.71, p = 0.0001), although the difference between the groups was not significant.

Table IV. FLACC score at pre- (T_0), during (T_{CPT}) and post (T_{120}) intervention.

CPT group	FLACC score*						
	T_0	T_{CPT}	T_{120}	$T_{CPT} - T_0$	p-value	$T_{120} - T_{CPT}$	p-value
Manual (n = 45)	3.56 ± 2.74	3.80 ± 2.4	0.84 ± 1.24	0.24 ± 1.2	0.175	−2.96 ± 2.55	0.0001
Mechanical (n = 42)	3.29 ± 2.61	3.71 ± 2.13	1.0 ± 1.47	0.43 ± 1.43	0.06	−2.71 ± 2.8	0.0001
p-value	0.64	0.86	0.59	0.50		0.66	

*Data presented as mean ± standard deviation, unless otherwise stated. *FLACC score between 0 to 10, with 0 = relaxed and comfortable; 1–3 = mild distress; 4–6 = moderate pain; and 7–10 = severe distress. CPT: chest physiotherapy; FLACC: Face, Leg, Activity, Cry, Consolability scale*

The daily mean Wang scores decreased significantly day by day from enrolment till Day 4 in both groups, from 8.4 to 4 ($p < 0.001$) in the manual group and from 8.6 to 4.5 ($p < 0.001$) in the mechanical group (Fig. 1). The number of patients on oxygen supplementation or respiratory support decreased from 12 (six in each group) at enrolment to 5 on Day 4. No adverse events such as bradycardia, desaturation, vomiting or rib fractures were observed during CPT. There was no difference in the median duration of hospitalisation between the manual and mechanical groups (4.4 days vs. 4.88 days, $p = 0.654$).

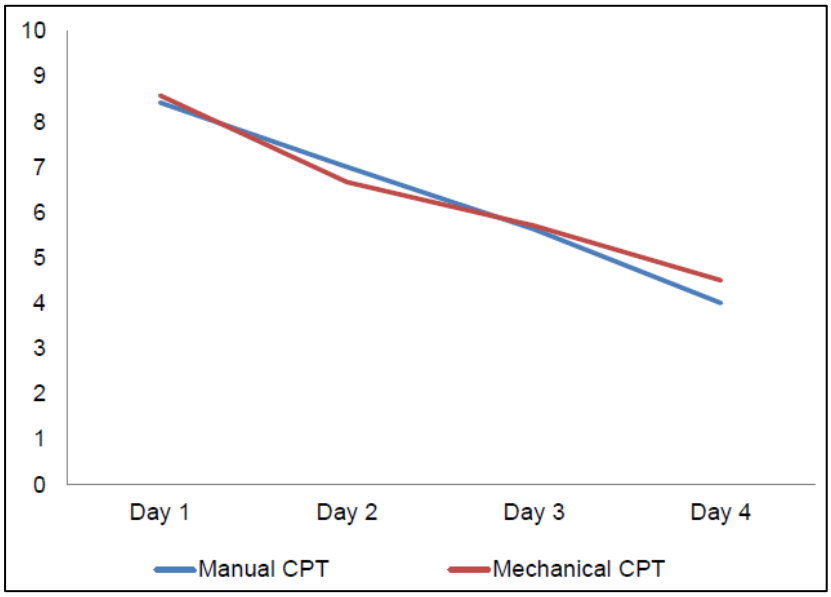

Fig. 1 Graph shows daily pre-intervention (T_0) Wang clinical severity scores.

DISCUSSION

In this study, we observed significant improvements in RR, oxygen saturation and mRDAI in patients who underwent either manual or mechanical CPT. Children using mechanical CPT had greater reduction in their RR and more improvement in oxygen saturation post intervention. No side-effects were noted, and there were improvements in the FLACC score after both interventions.

The baseline demographics in both groups were comparable for age, weight and severity of respiratory distress. While there was a male preponderance in the mechanical group, this is unlikely to have influenced the results. The median mRDAI score of 11 at enrolment indicated moderately severe respiratory distress and a need for CPT. The efficacy of the LEGA-Kid machine was comparable to that of manual CPT performed by an experienced chest physiotherapist. The main drawbacks to performing effective manual CPT include the need for trained personnel, variability in techniques and skills among personnel, time constraints and familial burden. The combination of percussion and vibrations provided by the LEGA-Kid machine could mimic manual CPT, which helps to dislodge loosened secretions. Maximum intrathoracic pressure was achieved when the percussor was pressed firmly and at right angles to the chest wall to make the voice quiver. The percussor was shown to maintain a higher and more constant intrathoracic pressure compared to the performance of three physiotherapists.(16)

Our results differ from those of previous studies that compared CPT versus no CPT in children less than 2 years old with severe bronchiolitis; no significant improvement in clinical severity was reported in children who received CPT compared to those who did not.(17-19) These studies, however, did not incorporate prior nebulisation with hypertonic saline. Of the 12 randomised controlled trials reviewed in the 2016 Cochrane review,(9) only one study(8) included the use of nebulised 3% saline with albuterol with or without CPT in patients with

moderately severe respiratory syncytial virus-bronchiolitis. An immediate reduction in wheezing and retractions was observed in patients who received CPT, with no impact on duration of hospitalisation.(8)

Despite the heterogeneity of the patients in our study, all of them retained airway secretions, which contributed to their respiratory distress. Nebulised hypertonic saline induces an osmotic flow of water in the inspissated mucous, thus reducing the viscosity of the mucous and oedema in the submucosal tissue.(20) Subsequent CPT assists in the clearance of the loosened secretions, resulting in improved tidal volume, a more effective cough, and further removal of secretions, which helps to make breathing immediately easier for the young child. This sequence of events explains the improvement in RR and better scores for the three components of mRDAI at $T_{120,}$ as compared to those at T_0. Our combined strategy of nebulised hypertonic saline followed by CPT differs from that of studies that investigated the efficacy of nebulised hypertonic saline alone in the management of LRTI.(21-23)

Both the manual and mechanical CPT procedures used in our study were well tolerated by the patients, as measured by the FLACC scale. Our patients' acceptance of CPT could be partially explained by the distraction methods used. The FLACC score was further reduced at T_{120}, indicating an improvement in overall condition post intervention. No adverse events were reported. The median length of stay in patients with acute bronchiolitis and bronchopneumonia was similar to those reported in the literature.(17,24)

The strengths of our study lie in the standardisation of CPT methods with the use of one trained physiotherapist to perform both the mechanical and manual CPT, and two physicians throughout the study – one to evaluate safety and tolerability, and the other to assess the efficacy of CPT. Furthermore, the latter physician was blinded to the method of CPT. However, our study was not without its limitations. First, it was limited by the lack of a control group with no CPT, which may have affected the interpretation of our results. We

were unable to have a control group, as our hospital's policy requires children below 2 years old with LRTI to be managed with regular CPT when needed. Furthermore, we did not conduct subsequent evaluations beyond two hours to determine whether the improvements observed were sustained; nonetheless, no child in the study deteriorated during or after CPT. Our study also did not set out to investigate the ease of the percussor versus conventional physiotherapy. Finally, our sample size was small but sufficient for a pilot study.

In summary, as an adjunct treatment for LRTI, CPT is safe and beneficial for mucociliary clearance and results in improvement of moderately severe respiratory distress. The LEGA-Kid percussor is better than manual CPT performed by experienced personnel. Further studies are needed to confirm these preliminary results.

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